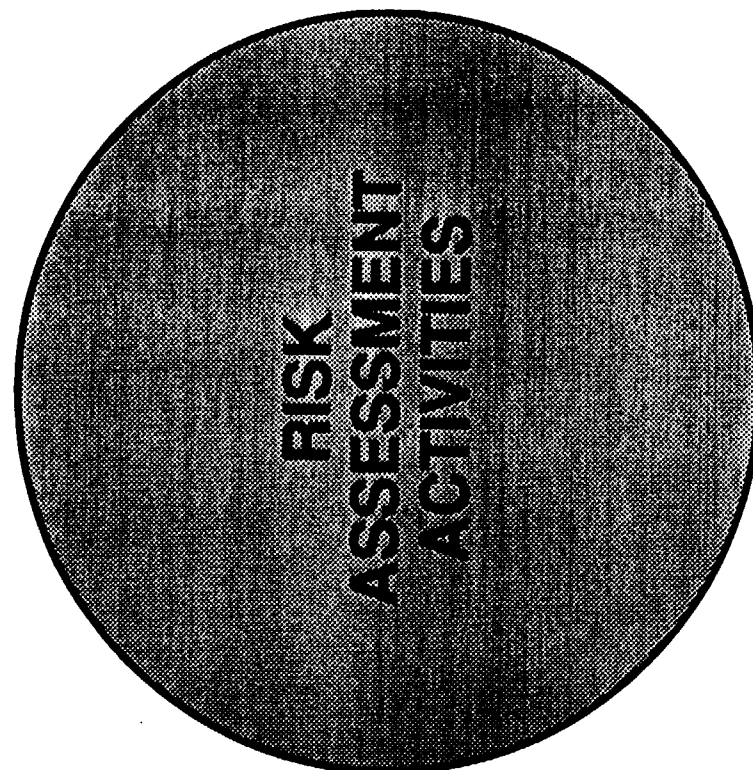


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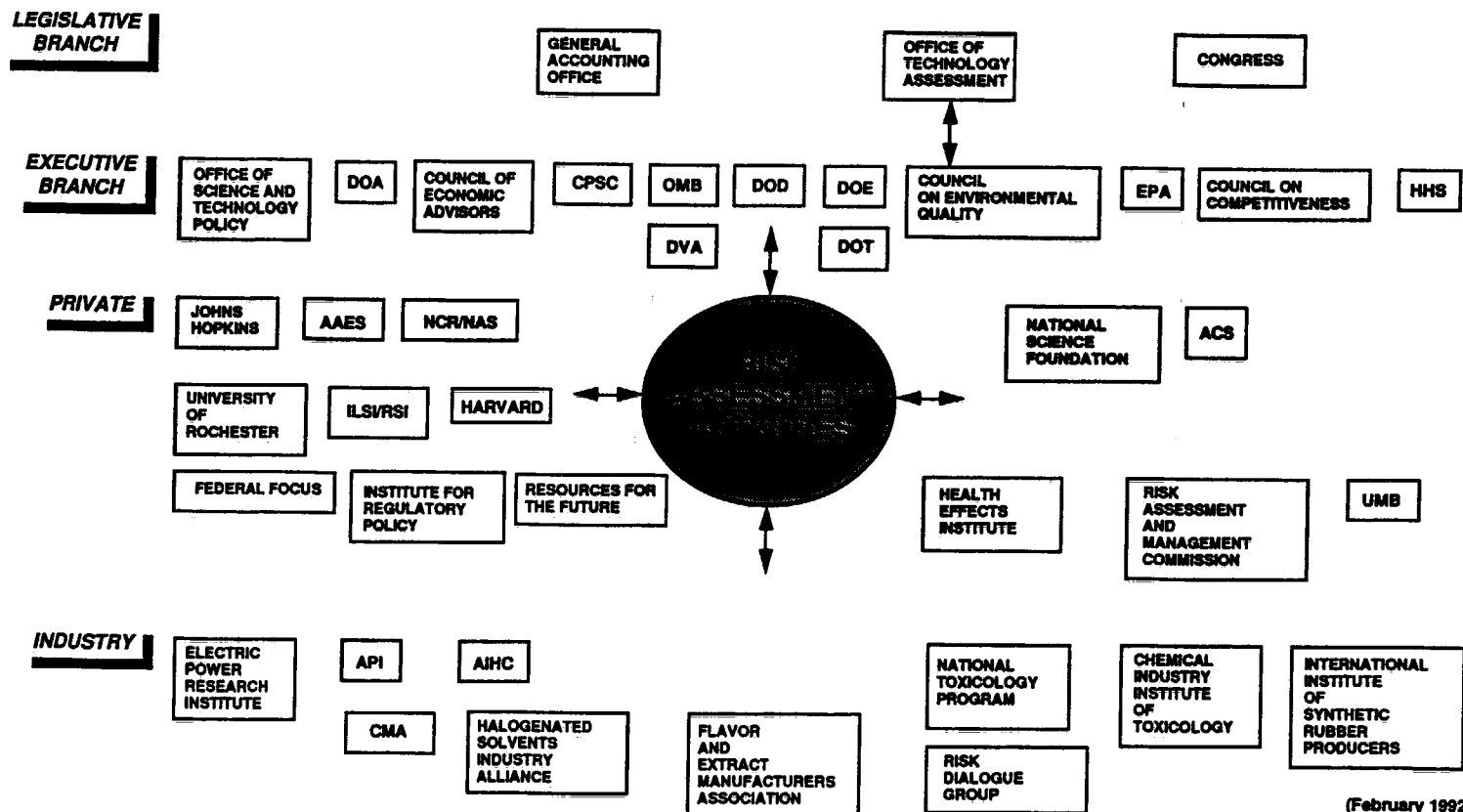
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## RISK ASSESSMENT ACTIVITIES



(February 1992)

2023480214

**RISK ASSESSMENT EFFORTS  
IN THE  
LEGISLATIVE BRANCH**

**2023480215**

## **OFFICE OF TECHNOLOGY ASSESSMENT (OTA)**

The Office of Technology Assessment (OTA) reports to the Congress on the scientific and technical impact of government policies and proposed legislative initiatives. OTA was created by the technology Assessment Act of 1972 to provide objective analyses of major public policy issues related to scientific and technological change. A bi-partisan 13 member Board governs the OTA. The Board includes 6 Senators appointed by the President pro tempore, 6 members of the House of Representatives appointed by the Speaker and the Director of OTA.

The Office's assessments explore complex issues involving science and technology, helping Congress resolve uncertainties and conflicting claims, identifying alternative policy options and providing foresight or early alert to new developments that could have important implications for future Federal policy.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- On February 7, 1992, the first meeting was held of the Advisory Panel on Research on Risk Assessment Methodology. The U.S. House of Representatives Energy and Commerce Committee and the House Science, Space and Technology Committee have sent OTA letters requesting a proposed study on an assessment of federal activities in risk assessment research, a comparison of how agencies set research priorities and choose projects to fund, an examination of research activities and results in several areas to analyze their impact on agency practice and a discussion of barriers to the incorporation of new knowledge into agency procedures. The assessment will be carried out from August 1991 to February 1993.
- Identifying and Controlling Immunotoxic Substances. (Biological Applications Program). In April 1990 OTA completed and released a report on neurotoxic compounds at the request of Senator Reid (D-NV). As a follow up, in April 1991, OTA released their assessment on the identification and control of immunotoxic substances. One point in the paper is the observation that federal programs have generally not regulated substances because of their immunotoxic effects or the risks arising from such effects.
- Genetic Monitoring and Screening in the Workplace. OTA has become involved in several workplace issues, specifically addressing worker health. The above mentioned report was released in October 1990 and OTA officials have noted that the report is likely to impact on future projects and federal risk management policies since improved genetic mapping and screening allow for selective determinations of individual risks.

- **Cleanup Worker Health Risks (Oceans and Environment Program).**
- **Biological Rhythms: Implications for the Worker. (Biological Applications Program). September 1991.**
- **Long Lived Legacy: Managing High Level and Transuranic Waste at the DOE Nuclear Weapons Complex. (Oceans and Environment Program). In May 1991, OTA released a report addressing the cleanup of the nuclear weapons production complexes. It focused on the cost effectiveness and probable success of the Department of Energy's approach. The report stated that (1) the program is regulatory driven, not health driven; (2) the steps taken to date do not reduce health risks; and (3) the design of the cleanup is unsatisfactory and embodies poor risk assessment techniques.**
- **Changing by Degrees: Steps to Reduce Greenhouse Gases. (Oceans and Environment Program). OTA has also released a study on global warming which examines the future impact of technologies required to achieve a 20% reduction in emissions. Currently, OTA is developing a study design which will focus on the assessment of assumptions underlying risk assessment methodologies.**

#### **FUNDING:**

**The Advisory Panel and research activities are funded by the Department of Energy (DOE), the Department of Health and Human Services (HHS), the Environmental Protection Agency (EPA), and the National Science Foundation (NSF). The majority of the OTA funding is from federal agencies which are responsible for a given issue.[Additional information being processed]**

2023480217

## **CONGRESS**

Congress addresses the regulation of environmental and safety risks in statutes and delegates regulatory responsibilities to federal agencies. The following is a list of the statutes related to environmental and safety risks, the agencies and the legislative responsibilities.

**Statute:** Atomic Energy Act, 42 U.S.C. 2011 et seq.  
**Responsible Agency:** NRC, EPA  
**Mandate:** Formulate standards to "protect the public health and safety: against radiation at nuclear power facilities and for handling of byproduct materials" (NRC); set standards for the "protection of the public health, safety, and environment" from uranium mill tailings and byproducts and other radiation hazards" (EPA)

-----

**Statute:** Comprehensive Environmental Response, Compensation and Liability Act ("Superfund"), 42 U.S.C. 9601 et seq.  
**Responsible Agency:** EPA  
**Mandate:** Hazardous waste cleanup levels must assure "protection of human health and the environment" against contaminants that "will, or may reasonably be anticipated to cause: certain adverse health effects, and must, under certain circumstances, meet standards set under other Acts, such as the Safe Drinking Water Act"

-----

**Statute:** Clean Air Act, 42 U.S.C. 7401 et seq.  
**Responsible Agency:** EPA  
**Mandate:** Issue ambient standards sufficient to "protect the public health: with an adequate margin of safety", issue "maximum achievable" standards for sources of hazardous pollutants which are "known or anticipated to cause adverse effects", and set supplemental emission standards if it is found that the "maximum achievable" standards do not provide an "ample margin of safety": (defined for known or potential carcinogens as a risk level of less than one in one million for the most exposed individual)

-----

**Statute:** Clean Water Act  
**Responsible Agency:** EPA  
**Mandate:** Prohibit discharges of pollutants in quantities "which may reasonably be anticipated to pose an unacceptable risk to human health or the environment" or "which present an imminent and substantial danger to the public health or welfare"

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**Statute:** Consumer Product Safety Act, 15 U.S.C. 2051 et seq.  
**Responsible Agency:** Consumer Product Safety Commission  
**Mandate:** Set standards for, or prohibit distribution of, "consumer products" (with certain exceptions such as pesticides, drugs, and foods covered by other laws) that present an "unreasonable risk" of "death, personal injury, or serious or frequent illness"

-----

**Statute:** Egg Products Inspection Act, 21 U.S.C. 1031 et seq.  
**Responsible Agency:** Department of Agriculture  
**Mandate:** Prevent distribution of eggs or egg products that may be "injurious to health", that are "unfit for human food", or are "unsafe" due to a poisonous or deleterious substance

-----

**Statute:** Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.  
**Responsible Agency:** Health and Human Services, EPA  
**Mandate:** Prohibit, inter alia, distribution of foods, food and color additives, drugs, medical devices and cosmetics that are "unsafe" or "injurious to health", set standards for environmental contaminants in food as "necessary for the protection of public health", set "safe" tolerances "to protect the public health" from pesticide residues on raw agricultural commodities (EPA sets the tolerances)

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**Statute:** Federal Hazardous Substances Act, 15 U.S.C. 1261 et seq.  
**Responsible Agency:** Consumer Products Safety Commission  
**Mandate:** Declare substances and articles to be "hazardous" which "may cause" substantial injury or illness as a result of "reasonably foreseeable" handling, use, ingestion, damage, or abuse (and "hazardous" substances and articles are prohibited from being introduced into interstate commerce)

**Statute:** Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq.  
**Responsible Agency:** EPA  
**Mandate:** Disallow use of pesticides that pose "any unreasonable risk to human health or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide"

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**Statute:** Federal Meat Inspection Act, 21 U.S.C. 601 et seq.  
**Responsible Agency:** Department of Agriculture  
**Mandate:** Prevent distribution of meat and meat food products that may be "injurious to health", "unfit for human food", or "unsafe" due to a poisonous or deleterious substance

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**Statute:** Federal Mine Safety and Health Act, 30 U.S.C. 801 et seq.  
**Responsible Agency:** Department of Labor  
**Mandate:** Set standards for the protection of life and prevention of injuries

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**Statute:** Hazardous Liquid Pipeline Safety Act, 49 U.S.C. 1671 et seq.  
**Responsible Agency:** Department of Transportation  
**Mandate:** Set "reasonable" and "safe" transportation of materials posing an "unreasonable risk"

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**Statute:** Lead-Based Paint Poisoning Prevention Act, 42 U.S.C. 4801 et seq.  
**Responsible Agency:** Department of Housing and Urban Development, Health and Human Services, Consumer Product Safety Commission  
**Mandate:** Eliminate as far as practicable the hazards associated with unsafe levels of lead-based paint in housing

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**Statute:** Lead Contamination Control Act of 1988, 42 U.S.C. 300j-21 et seq.  
**Responsible Agency:** EPA, CPSC  
**Mandate:** Recall and prevent distribution of drinking water coolers containing lead

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**Statute:** Marine Protection, Research, and Sanctuaries Act, 16 U.S.C. 1431 et seq.  
**Responsible Agency:** EPA, Department of the Army  
**Mandate:** Do not issue permits for ocean dumping if it would "unreasonably degrade or endanger human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities"

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**Statute:** Motor Carrier Safety Act, 49 U.S.C. 2501 et seq.  
**Responsible Agency:** Department of Transportation  
**Mandate:** Issue "safety standards"

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**Statute:** National Traffic and Motor Vehicle Safety Act, 15 U.S.C. 1381 et seq.  
**Responsible Agency:** Department of Transportation  
**Mandate:** Prevent "unreasonable risks"

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**Statute:** Natural Gas Pipeline Safety Act, 49 U.S.C. 2001 et seq.  
**Responsible Agency:** Department of Transportation  
**Mandate:** Set "reasonable" and "appropriate" standards for protection of public safety

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**Statute:** Nuclear Waste Policy Act, 42 U.S.C. 10101 et seq.  
**Responsible Agency:** EPA  
**Mandate:** Set standards "for protection of the general environment" from radioactive releases from high-level radioactive waste facilities

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**Statute:** Occupational Safety and Health Act, 29 U.S.C. 651 et seq.  
**Responsible Agency:** Department of Labor  
**Mandate:** Set exposure standards at a level "which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity...for the period of his working life" with a goal of "attainment of the highest degree of health and safety protection" as "reasonably necessary or appropriate to provide safe or healthful employment and places of employment"

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**Statute:** Poison Prevention Packaging Act, 15 U.S.C. 1471 et seq.  
**Responsible Agency:** CPSC  
**Mandate:** Establish special packaging standards for household substances as determined to be necessary to "protect against serious personal injury or serious illness"

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**Statute:** Poultry Products Inspection Act, 21 U.S.C. 451 et seq.  
**Responsible Agency:** Department of Agriculture  
**Mandate:** Prevent distribution of poultry products that may be "injurious to health", "unfit for human food", or "unsafe" due to a poisonous or deleterious substance

-----

**Statute:** Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901 et seq.  
**Responsible Agency:** EPA  
**Mandate:** Control disposal of solid wastes which "may cause, or significantly contribute to an increase in mortality or...serious irreversible, or incapacitating reversible, illness; or ...pose a substantial present or potential hazard to human health or the environment" or which "endanger health [when present in excess of certain levels]"

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**Statute:** Safe Drinking Water Act, 42 U.S.C. 300f et seq.  
**Responsible Agency:** EPA  
**Mandate:** Set maximum contaminant level goals (MCLGs) to prevent "known or anticipated adverse [health] effects" with an "adequate margin of safety", and set maximum contaminant levels "as close as feasible" to the MCLGs

**Statute:** Toxic Substances Control Act, 7 U.S.C. 136 et seq.  
**Responsible Agency:** EPA  
**Mandate:** Prevent "unreasonable risk of injury to health or the environment" from chemical substances or mixtures (as defined, with specified exceptions such as pesticides, drugs, and food additives)

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## **GENERAL ACCOUNTING OFFICE (GAO)**

The Government Accounting Office (GAO) is the investigative arm of Congress and is charged with examining all matters relating to the receipt and disbursement of public funds. The GAO was established by the Budget and Accounting Act of 1921 to independently audit government agencies. GAO assists congressional committees in developing statements of legislative objectives and goals and, assists them in analyzing and assessing Federal agency programs and activities. Under the Energy Policy and Conservation Act of 1975, GAO is empowered to conduct verification of energy related information developed by private business concerns if asked by any committee having legislative or oversight responsibilities for energy matters. As a result of the energy responsibilities, GAO has become more involved in risk issues.

The GAO is required to do work requested by Congressional committee chairmen. Other assignments are initiated pursuant to standing committees, individual member requests, and some assignments are independently undertaken in accordance with GAO's basic legislative responsibilities. Some of the questions the GAO considers as part of an audit or evaluation include:

- Are government programs being operated in compliance with applicable laws and regulations, and is the data furnished to the Congress on these programs accurate;
- Do opportunities exist to eliminate waste and inefficient use of public funds?
- Are programs achieving desired results, or are changes needed in government policies or management.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

1. Technical Risk Assessments: the Status of Current DOD Efforts.
2. New Risk Assessment Program Could Help Evaluate Inspection Cycle.
3. Army's Risk Assessment of Chemical Munitions Transportation.
4. DOD's Risk Assessment and Safeguards Management of Chemical and Biological Warfare Research and Development Facilities.

### **FUNDING:**

[Information being processed]

## **RISK ASSESSMENT EFFORTS**

### **IN THE**

### **EXECUTIVE BRANCH**

Under the authority of the Reorganization Act of 1939, various agencies were transferred to the Executive Office of the President. Executive Order 8248, established the divisions of the Executive Office and defined their functions. Subsequently, Presidents have used Executive Orders, reorganization plans and legislative initiatives to reorganize the Executive Office to make its composition compatible with the goals of their administrations.

## **OFFICE OF SCIENCE AND TECHNOLOGY POLICY (OSTP)**

The Office of Science and Technology Policy (OSTP) was established within the Executive Office of the President by the National Science and Technology Policy, Organization, and Priorities Act of 1976. The Office serves as a source of scientific, engineering and technological analysis and judgement for the President with respect to major policies, plans, and programs of the Federal Government. One of OSTP's missions is to advise the President and evaluate the scale, quality, and effectiveness of the Federal effort in science and technology. In past years, OSTP has been involved in the analysis of risk related issues. More recently, however, they have taken on a more active approach to evaluating Federal efforts on risk assessment activities.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The Director of the OSTP chairs an inter-agency Federal Coordinating Council on Science, Engineering and Technology (FCCSET). FCCSET is a Cabinet level group which is playing an increasingly important role in risk assessment issues. An Ad Hoc Working Group on Risk Assessment was established under FCCSET and is chaired by the Deputy Administrator of the EPA.
- The purpose of the Ad Hoc Working Group is to "seek agency consensus on common principles that these agencies can apply in their approaches to risk assessment". The Working Group reports directly to FCCSET.
- FCCSET also has a Committee on Life Sciences and Health, which is chaired by the Department of Health and Human Services (HHS) Assistant Secretary for Health. The Committee has a Subcommittee on Risk Assessment co-chaired by officials from HHS and EPA. The Subcommittee has a large representation of scientists from all the federal agencies and serves as staff for the Council's Ad Hoc Working Group. The Subcommittee has begun work on a review of the 1985 OSTP cancer document, issues concerning reproductive toxicity and neurotoxicity risk assessment and risk assessment research needs.

### **FUNDING:**

[Information being processed]

## **COUNCIL ON ENVIRONMENTAL QUALITY (CEQ)**

The Council on Environmental Quality (CEQ) was established by the National Environmental Policy Act (NEPA) of 1969 to formulate and recommend national policies to promote the improvement of the quality of the environment. Additional responsibilities were provided by the Environmental Quality Improvement Act of 1970. The Council consists of three members appointed by the President with one member designated as Chairman. The Council Chairman participates in Domestic Policy Council, Economic Policy Council and other Cabinet level meetings. Some of the current issues the Council is working on include global change, recycling, risk assessment, pollution prevention, wetlands protection, energy conservation, and Soviet-U.S. cooperation.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- In 1989, CEQ released a publication entitled, "Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks" which covers all aspects of risk assessment and risk communication, with emphasis on cancer risks and includes a number of discussions of key issues as they relate to specific chemicals and exposure situations.
- Also, the Council's 21st Annual Report "Environmental Quality" demonstrates increasing attention to the economic implications of environmental regulation.

### **FUNDING:**

[Information being processed]

## **COUNCIL ON COMPETITIVENESS**

The costs of federal regulation are significant. Though estimates vary, current federal regulations can impose direct costs on the U.S. economy at several hundred billion dollars per year. The Council on Competitiveness was established in March 1989 to participate in the consideration of federal regulations. The Council is chaired by the Vice President, and its permanent members are the Attorney General, and Chairman Pro Tempore of the Domestic Policy Council, the Secretary of the Treasury and Chairman Pro Tempore of the Economic Policy Council, the Director of the Office of Management and Budget, the Chairman of the Council of Economic Advisors, the Secretary of Commerce, and the President's Chief of Staff.

Additional Cabinet members and Senior officials, including the Assistant to the President for Science and Technology, the Administrator of the EPA, the Chairman of the Council on Environmental Quality, and the Director of the National Science Foundation are invited to participate in the consideration of specific topics.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- In August 1990, the Vice President's office issued four "Principles of Regulatory Review for Biotechnology" developed by the Council on Competitiveness. The first three principles apply to biotechnology:
  - (1) products that pose little or no risk should not be subject to unnecessary agency regulatory review;
  - (2) agency regulatory review of biotechnology products should minimize regulatory burdens, and
  - (3) performance standards are preferred over design standards.
- The fourth principle is applicable to all environmental and health regulations and states that the performance standards are preferred over design standards.
- The Council on Competitiveness has been working through a Biotechnology Working Group to develop guidelines and clarification as to what types of activities will be subject to regulatory oversight.
- In 1990, the President asked the Council to oversee the regulatory review process as set out in Executive Order 12291. In a March 1991 memo to federal agencies, the Council requested that agencies send strategy statements, guidelines, policy manuals, grant and loan procedures, advance notices of proposed rulemaking, press releases and other documents to OMB under its authority in Executive Order 12291 to review rules before their public release.

- In January 1992, in a memorandum to the Secretaries of the Department of the Interior, the Department of Agriculture, the Department of Energy, the Administrator of the EPA, the Chairman of the Federal Energy Regulatory Commission, and the Chairman of the Nuclear Regulatory Commission, the President requested a 90 day moratorium and review of ongoing regulations in their respective agencies. OMB and the Council on Competitiveness were designated as the coordinating points for the moratorium and review.

**FUNDING:**

[Information being processed]

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## **COUNCIL OF ECONOMIC ADVISORS**

The Council of Economic Advisors was established by the Employment Act of 1946. It now functions under that statute and Reorganization Plan Number 9 of 1953. The Council consists of members appointed by the President by and with the advice and consent of the Senate. The Council analyzes the national economy and advises the President on economic developments, appraises the economic programs and policies of the Federal government, recommends to the President policies for economic growth and stability, and assists in the preparation of the economic reports by the President to the Congress.

The Council has shown a continuing interest in the impact of risk issues on the nation's economic productivity and competitiveness.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- In its 1990 Annual Report, the Council enunciated three principles for environmental regulation:
  - (1) goals for pollution abatement and risk reduction should be based on a comparison of the costs and benefits involved. Elimination of all risk is almost never a sensible goal;
  - (2) where possible, market based approaches that provide flexibility, encourage innovation, and support economic growth should be used to achieve environmental goals in a cost effective manner; and
  - (3) government policy should encourage the development and sharing of scientific and technical information relevant to environmental quality issues.

### **FUNDING:**

[Information being processed]

2023480230

## **OFFICE OF MANAGEMENT AND BUDGET (OMB)**

The Office of Management and Budget (OMB) was established in the Executive Office of the President by Reorganization Plan Number 2 of 1970. Reorganization Plan Number 1 of 1977 and Executive orders issued after that Plan amended further the functions of the Office. Basically, the function of the Office is to develop and maintain effective government by reviewing the organizational structure and management procedures of the Executive Branch to ensure that they produce the intended results. The Office also keeps the President informed of the progress of activities by government agencies with respect to work proposed, initiated, and completed, together with the relative timing of work between the agencies of the government.

OMB ensures that the work programs of the agencies of the Executive Branch may be coordinated and that the monies appropriated by the Congress may be expended in the most economical manner with the least possible overlapping and duplication of effort. Additionally, OMB assists in the development of regulatory reform proposals.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- In the government publication entitled, "Regulatory Program of the U.S. Government, April 1, 1990-March 31, 1991", OMB took issue with what it termed overly conservative risk assessment practices employed by EPA.
- As a follow up, the recently released Fiscal Year 1992 Administration budget crafted by OMB has also adopted a risk management budgeting pilot program for seven agencies: the Department of Agriculture, the Food and Drug Administration, the National Ocean and Atmospheric Administration, the Occupational Safety and Health Administration, the Health Care Financing Administration, the EPA and the Department of Transportation.
- The current OMB Director publicly states that risk management budgeting is a conceptually sound way to approach issues and that OMB intends to do more of it in order to ensure that resources are allocated to reducing the most serious risks in the most cost-effective way.
- In a March 1991 memo to federal agencies, the Council requested that agencies send strategy statements, guidelines, policy manuals, grant and loan procedures, advance notices of proposed rulemaking, press releases and other documents to OMB under its authority in Executive Order 12291 to review rules before their public release.

2023480231

- In January 1992, in a memorandum to the Secretaries of the Department of the Interior, the Department of Agriculture, the Department of Energy, the Administrator of the EPA, the Chairman of the Federal Energy Regulatory Commission, and the Chairman of the Nuclear Regulatory Commission, the President requested a 90 day moratorium and review of ongoing regulations in their respective agencies. OMB and the Council on Competitiveness were designated as the coordinating points for the moratorium and review.

**FUNDING:**

[Information being processed]

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

The Department of Health, Education and Welfare was created on April 11, 1953. Under the Department of Education Organization Act of 1979, the Department was redesignated as the Department of Health and Human Services (HHS). HHS advises the President on health, welfare, and income security plans, policies and programs of the federal government. The Secretary administers this function through his office and five Operating Divisions, which include: the Public Health Service (PHS), the Social Security Administration, the Health Care Financing Administration, the Office of Human Development Services, and the Office of Community Services. The Public Health Service (PHS) is where the majority of the technical issues are dealt with by the Department. The mission of the PHS is to promote the protection and advancement of the Nation's physical and mental health.

Major components of the PHS include: the Agency for health Care Policy and research, the Alcohol, Drug Abuse, and Mental Health Administration, the National Institute on Drug Abuse, the national Institute of Mental Health, the Office for Substance Abuse Prevention, the Office for Treatment Improvement, the Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control (CDC), Center for Environmental Health, Center for Health Promotion and Education, National Institute of Occupational Safety and Health (NIOSH), Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition, National Center for Toxicological Research, National Institutes of Health, National Cancer Institute, and the National Institute for Environmental Health Sciences.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- HHS is undertaking a complete review of its risk assessment methodologies and risk management policies, particularly in the area of food safety, with a view to making improvements and obtaining greater consistency among all its programs.
  - ATSDR has been developing a Health Assessment Guidance manual for Superfund and RCRA sites. HHS, EPA and the Department of Agriculture are also working with the Executive Office of the President in developing recommendations for new food safety legislation.
1. Morbidity Risk Assessment in the Elderly.
  2. Social Competence Risk Assessment - Mother, Child Factors.
  3. Cardiovascular Risk Assessment and Modification (Human).

4. **Ultrasound Screening and Risk Assessment of Pregnancy.**
5. **Biologic Monitoring/ Risk Assessment in an Exposed Cohort (Human).**
6. **Knowledge Elicitation for Developmental Risk Assessment (Human).**
7. **Development of an Automated Risk Assessment Support System for Child Protective Services.**
8. **Quantitative Risk Assessment.**
9. **Epidemiology - Risk Assessment.**
10. **Cancer, and Injury Risk Assessment for Radionuclides.**
11. **Genetic Susceptibility to Second Primary Tumors - Risk Assessment Model.**
12. **Cancer Mechanisms - Implications for Risk Assessment.**
13. **Control of Colon Cancer Through Familial Risk Assessment.**
14. **Bacterial Risk Assessment for Periodontal Disease (Human, Mice).**
15. **Cholesterol: Cardiac Risk Assessment. September 1970-May 1990. (A Bibliography From the NTIS Database). June 1990.**
16. **In Vitro Studies of Chemical Effects on Gap-Junctional Communication: Role of Biotransformation in Toxicant Detection and Use of Assays in Risk Assessment. C 1990.**

**FUNDING:**

**[Information being processed]**

2023480234

## **DEPARTMENT OF DEFENSE (DOD)**

The Department of Defense (DOD) was established as an executive department of the government by the National Security Act Amendments of 1949. Since that time there have been numerous reorganization plans and amendments made to the Act. The Department of Defense is responsible for providing the military forces needed to deter war and protect the security of our country. Every State has some defense activities occupying some type of military facility.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- There are a number of identified DOD hazardous waste sites and the military is asking toxicologists to address the critical issues, such as identifying the human health risks from environmental contamination and communicating the risks to Congress and the public.
- DOD has human exposure data which needs to be made available to those regulatory agencies, EPA, OSHA and NIOSH, which do the multitude of risk assessments. The military has a wealth of data and are researching ways to integrate it between groups within the Department. For example, the Air Force has recommended the formation of a depository of environmental data that resides within the Air Force. The Army and EPA are working closely together on drinking water matters. The Surgeon General for each of the services has the responsibility for maintaining the health effects data.

### **FUNDING:**

[Information being processed]

## **DEPARTMENT OF ENERGY (DOE)**

The Department of Energy (DOE) was established by the Department of Energy Organization Act approved August 1977. DOE provides the framework for a comprehensive and balanced national energy plan through the coordination and administration of the energy functions of the Federal government. The Department is responsible for long term, high risk research and development of energy technology; the marketing of Federal power; energy conservation; the nuclear weapons program; energy regulatory programs; and a central energy data collection and analysis program.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

1. Determination of the Road Transport Risk in Waste Management By Nuclear Plants, Integrated Waste Management Plans or Other Waste Management Technologies Within PSE II.
2. A Hit-Size-Effectiveness Factor (HSEF) for Chromosome Aberrations.
3. Radiation Carcinogenesis: Dose-Effect Relationships of Varying Energies of Neutrons in Leukemogenesis.
4. Risk Analysis for the Transport and Storage of Radioactive Kr-85.
5. Evaluation of the Capacitance of the Results of Risk Analysis of Nuclear Plants.
6. Lung Cancer Risk From Inhalation of Radon and Other Pollutants in Rats.
7. Assessment of Radiation Consequences with Regard to the Natural Radioactivity Consequences.
8. Indoor Atmospheric Chemistry: Interactions of Radon with Other Gaseous Pollutants.
9. Evaluation of Applications for Risk Study Phase B.
10. Comparative Hazards of Radon and Thoron in Indoor Air.
11. Comparison of Nuclear Risks with Other Technical Risks.
12. Occupational Safety.
13. Radiation Carcinogenic Time-Dose Relation.

14. Interspecies Extrapolation and Risk Assessment in Carcinogenesis.
15. Effects of Age at Exposure to Inhaled Radioactive Aerosols.
16. Mechanisms of Alpha-Particle-Induced Carcinogenesis.
17. Influence of Radiation Dose Factors on the Effects of Inhaled Beta Emitters.
18. Dose-Response Relationships for Inhaled Low-LET Radionuclides.
19. Scientific Work on the Applicability of Dispersion Calculations of the non-Gaussian Type to the Risk Analysis at a Reactor Accident.
20. Risk Analysis.
21. Safety and Biological Risks of the Nuclear Fuel Cycle.
22. In-depth Risk Analysis of the Solvent Off-Gas System of the Large Reprocessing Plant-Initial Financing.
23. Independent Review of DOE's Probabilistic Risk Assessments (PRA's)
24. German Risk Study-Phase B.
25. Immediate Fundamental Problems Concerning the Risk of Damage Caused by Ionizing Radiation.
26. Dynamic Behavior of Radon Daughters in the Environment.
27. Comparative Risk Studies for Special Containment Concepts.
28. Experimental Links Between Internal Emitters and Human Lung Cancers.
29. Movement of Highly Active Waste (TS3.1) -Projected Risk Analysis-Safety Analysis of the Solidification of Highly Active Waste and Evidence of the Acceptability for Final Storage.
30. HAW Mobilization (TS3.1).-Project Risk Analysis for Back and Fuel Cycle.- Safety Analysis of the HAW Solidification Products and Demonstration of the Concept for Ultimate Disposal Being Suitable for Licensing.
31. Carcinogenicity of Mixtures.

32. Completion of System Analytical and Mathematical Basis for Risk Analysis of the Nuclear Fuel Circuit and System Analysis Accompanying Development of Reprocessing and Spent Fuel System (PSE II).
33. Completion of the Fundamentals of the Systems Analysis and Mathematics for a Risk Assessment of the Nuclear Fuel Cycle and Development Related Systems Analysis for Reprocessing and Back End Fuel Cycle Facilities.
34. Populations at Risk to Environmental Pollution.
35. Risk Assessment for the Back End Fuel Cycle (PSE)-1) Radiation Exposure of the Population via Drinking Water and Food Chains; 2) Propagation of Radioactive Substances in the Ground; 3) Propagation of Radioactive Material in the Upper Ground Water Conductor.
36. Calculation of the Population Dose After Incidents at Sites for Radioactive Waste Facilities.
37. Importance of Non-uniformity of Dose From Inhaled Plutonium.
38. Characterization of Airborne Radon Concentrations.
39. Air Pollutant Exposures In Buildings.
40. Radiation Dose to Critical Lung Cells From Radon.
41. Techniques for Assessing the Frequency and Consequences of Hazardous Occurrences.
42. Indoor Air Quality Risk Assessment Workshop.
43. Inhaled Plutonium Oxide in Dogs.
44. Works for the German Risk Study-Phase B; Loss of Coolant Incidents; Releasing Events and Sequence of Events for Loss of Coolant Incidents.
45. Atmospheric Transport and Risk Analysis.
46. Probabilistic Risk Assessment Technical Review.
47. Molecular Cytogenetics.
48. Detailed Investigations of Possible Dangers Due to Mutual Influencing of Several Nuclear Plants of One Site and Estimation of the Share of Risk.

49. **Biochemical Mechanisms of Chemically Induced Health Effects.**
50. **Risk Assessment of Outburst Prone Coal Seams Based on a Geological and Structural Index Classification.**
51. **Simplified Risk Considerations For Plant Components and Media Supply Facilities of a Reprocessing Plant.**
52. **Mammalian Genetics.**
53. **Risk Analysis in Mine Project Evaluation.**
54. **Population Hazards of Nuclear Facilities.**
55. **Spontaneous Combustion Risk Classification in Coal Seams.**
56. **Potential Health Risks From Inhaled or Ingested Methanol.**
57. **Analysis of the Fundamentals of Risk Comparisons Between the Natural Radiation Risk, the Radiation Risk from Nuclear Power Generation, and the Overall Risk From Power Generation From Coal.**
58. **Scientific Issues in Quantitative Cancer Risk Assessment.**
59. **Probabilistic Risk Assessment.**
60. **Development and Application of Automated Calorimeters for Spontaneous Combustion Risk Evaluations of Minerals.**
61. **Effects of Respirable Fly Ash In Vitro and In Vivo Inhalation Experiments.**
62. **Human Health Effects of Plutonium.**
63. **Risk Assessment of the 1000 MWE-3-Loop Concept for KWU's PWR-Type Reactors.**
64. **Probabilistic Error Analysis of the Results of Complex Computer Models.**
65. **Risk Analysis of Spent Fuel Storage in the Waste Disposal Center.**
66. **Risk Analysis PAMELA, HAW and MAW Storage Tank Building, MAW Solidification, MAVVA, Compilation and Processing of Data Concerning the Amounts and Types of Radioactive Wastes.**

67. **Preclosure Risk Assessment Methodology.**
68. **Assessment of the Risk of Pulverized Coal Storage.**
69. **Study of Respirable Dust Concentrations Liable to Affect Individual Miners at Their Work Stations.**
70. **Risk Assessment of An Airplane Crash Onto the Location of an Uranium Upgrading Plant.**
71. **HVAC Fault Tree Analysis For WIPP Integrated Risk Assessment.**
72. **Comparison Of Two Risk Assessment Methodologies For High Level Waste Disposal In Unsaturated Media. February 1991.**
73. **Causes of Disagreement And Conditions of Agreement In Risk Assessment. January 1990.**
74. **Water Reactor Safety Information Meeting (18th). Volume 2. Severe Accident Research; Accident Management; Probabilistic Risk Assessment Topics; Individual Plant Examination Program and Other Issues. April 1991.**
75. **Basic Theory and Methods of Dosimetry For Use In Risk Assessment Of Genotoxic Chemicals. Annual Technical Progress Report. 1990.**
76. **Probabilistic Risk Assessment for the K-65 Silos at the FMPC. November 1990.**
77. **Assessing Ecological Impacts of Hazardous Waste Sites On Marine Systems: The Allen Harbor Risk Assessment Pilot Study. November 1990.**
78. **Initiating Event Identification and Screening for Nuclear Waste Repository Preclosure Risk Assessment. 1990.**
79. **Risk Assessment of Indoor Refueling and Servicing of CNG-Fueled Mass Transit Buses. November 1990.**
80. **Risk Assessment of Indoor Refueling and Servicing of CNG-Fueled Mass Transit Buses. Phase 2. Final Report. Volume 1. December 1988-November 1990. August 1990.**
81. **Risk Assessment of Indoor Refueling and Servicing of CNG-Fueled Mass Transit Buses. Phase 2. Final Report. Volume 2. Fault Tree Models. December 1988-November 1990. August 1990.**

82. **Melcor 1.8.0: A Computer Code for Nuclear Reactor Severe Accident Source Term and Risk Assessment Analyses.** January 1991.
83. **Risk Assessment of New Chemical Substances: Applicability of EXAMS II As An Advanced Water Quality Model.** May 1990.
84. **Comparative Risk Assessment of Radiation and Other Mutagenic Agents-Low Dose Relative Risk of Different Ionizing Radiations and Comparison With UV Radiation.** April 1990.
85. **Hanford Waste Vitrification Systems Risk Assessment Action Plan.** November 1990.
86. **Probabilistic Risk Assessment Techniques Help Identify Potential Hazards in Vapor Vacuum Extraction.** 1991.
87. **Probabilistic Risk Assessment Techniques Help In Identifying Optimal Equipment Design For In-Situ Vitrification.** 1990.
88. **Reduced-Scope Seismic Analysis Accomplished Using Probabilistic Risk Assessment Techniques.** 1990.
89. **Risk Assessment the DOE Way.** January 1991.
90. **Results of the Level 1 Probabilistic Risk Assessment (PRA) of Internal Events For Heavy Water Production Reactors.** 1990.
91. **Biological Safety Factors In Toxicological Risk Assessment.** C 1990.
92. **Level III Probabilistic Risk Assessment For N Reactor. Volume 3, Appendices D and E.** April 1990.
93. **Level III Probabilistic Risk Assessment For N Reactor. Volume 2, Appendices A, B, and C.** April 1990.
94. **Level III Probabilistic Risk Assessment For N Reactor. Volume 1.** April 1990.
95. **Role of Risk Assessment and Safety Analysis in Integrated Safety Assessments.** 1990.
96. **Application of Probabilistic Risk Assessment Techniques During Design Phase for Dry Storage Casks.** 1990.

97. **Structural Risk Assessment and Aircraft Fleet Maintenance. March 1990.**
98. **N Reactor External Events Probabilistic Risk Assessment Using NUREG-1150 Methods. 1990.**
99. **EE Microfabrication Facility Toxic Gas System. A Probabilistic Risk Assessment Using Human Reliability Analysis Methods. July 1990.**
100. **N Reactor Probabilistic Risk Assessment Supporting Calculations. Volume 3, Appendices H-U. June 1990.**
101. **Fire Risk Assessment Method: Guide To The Risk Methodology Software. September 1990.**
102. **Application of Phenomenological Calculations to the N Reactor Probabilistic Risk Assessment. 1990.**
103. **LAVA/CIS Version 2.0 A Software System for Vulnerability and Risk Assessment. 1990.**
104. **DOE Safety Goals Comparison Using NUREG-1150 PRA (Probabilistic Risk Assessment) Methodology. June 1990.**
105. **Relevance of Risk Assessment to Public Health Aspects of the National Energy Policy. 6 July 1990.**
106. **Toluene Model for Hydrocarbon Risk Assessment. 29 May 1990.**
107. **Vapor Cloud Modelling in the Risk Assessment of Major Toxic Hazards: Effect of Relative Humidity. C 1990.**
108. **N Reactor Probabilistic Risk Assessment Supporting Calculations. Volume 1. Main Report. June 1990.**
109. **N Reactor Probabilistic Risk Assessment Supporting Calculations. Volume 2. Appendices A-G. June 1990.**
110. **Pathogen Risk Assessment For Land Application of Municipal Sludge. September 1990.**
111. **N Reactor Level 1 Probabilistic Risk Assessment. Final Report. May 1990.**
112. **Techniques for Developing A System Safety Risk Assessment Model. April 1990.**

113. Strategic Risk Assessment: Where We Are And How We Got There. April 1990.
114. Lawrence Livermore National Laboratory RCRA Part B Health Risk Assessment. Phase 2, Hazardous Waste Management Units: Appendices. 20 February 1990.
115. Lawrence Livermore National Laboratory RCRA Part B Health Risk Assessment. Phase 2, Hazardous Waste Management Units. 20 February 1990.
116. Radiological Risk Assessment of a Radioactively Contaminated Site. 1990.
117. U.S. Department of Energy Risk Assessment Methodology. Volume 1. DOE Risk Assessment Guideline Instructions, Resource Table, and Completed Sample. Volume 2. DOE Risk Assessment Worksheets. May 1990.
118. Fire Risk Assessment Method: Case Study 4, Interior Finish in Restaurants. May 1990.
119. Radiological Risk Assessment For Radioactive Contamination at Landfill Site. 1990.
120. Fire Risk Assessment Method: Description of Methodology. May 1990.
121. Fire Risk Assessment Method: Case Study 3, Concealed Combustibles in Hotels. June 1990.
122. Fire Risk Assessment Method: Case Study 2, Carpet In Offices. May 1990.
123. Fire Risk Assessment Method: Case Study 1, Upholstered Furniture in Residences. June 1990.
124. Review of the Chronic Exposure Pathway Models in MACCS and Several Other Well Known Probabilistic Risk Assessment Models. June 1990.
125. Basic Theory and Methods of Dosimetry For Use In Risk Assessment of Genotoxic Chemicals. Annual Technical Progress Report. 15 February 1990.
126. Data Banks For Risk Assessment At The Savannah River Site. 1990.
127. Proceedings of the U.S. Nuclear Regulatory Commission Water Reactor Safety Information Meeting (17th), October 23-25, 1989. Volume 2.

**Accident Management, Severe Accident Research, Earth Sciences,  
Probabilistic Risk Management, Seismic and Structural Engineering. March  
1990.**

- 128. Application of Risk Assessment in Upgrading Safety and Quality of  
Radiochemical Operations. 1990.**
- 129. PRAMIS: Probability Risk Assessment Model Integration Systems. User's  
Guide. May 1990.**
- 130. Evaluation of Severe Accident Risks.**
- 131. Severe Accident Risks: An Assessment for Five Nuclear Power Plants.**

**FUNDING:**

**[Information being processed]**

## **DEPARTMENT OF AGRICULTURE (DOA)**

A May 15, 1862 act of Congress created the Department of Agriculture (DOA). In 1889 the powers and duties of the Department were enlarged. The Department works to enhance the environment and to maintain production capacity by helping landowners protect the soil, water, forests, and other natural resources.

The offices at DOA involved in risk assessment efforts include: the Agricultural Marketing Service, the Food Safety Inspection Service, the National Biological Impact Assessment Program, Cooperative State Research Service, and within the Office of the Secretary of DOA, their liaison to the Council on Competitiveness.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The Department of Agriculture, HHS and EPA are working with the Executive Office of the President in developing recommendations for food safety legislation.
  - The National Biological Impact Assessment Program of the Cooperative State Research Service is working on a risk assessment project entitled, "Identification of Data Systems for Risk Assessments".
1. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (Ohio State University)
  2. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (University of Florida)
  3. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (Virginia Polytechnic Institute)
  4. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (North Carolina State University)
  5. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (University of California)
  6. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (University of Arkansas)
  7. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (University of Minnesota)
  8. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (University of Kentucky)

9. **Investigations of Selected Foreign Plant Pathogens Which Pose a Threat to U.S. Agriculture.**
10. **Assessment of Cytochrome P-450 and Halomethane Activation.**
11. **Pilot Computer Database of Exotic Fungi on High Priority Plant Risk Assessments.**
12. **Minimizing Occupational Exposure to Pesticides.**
13. **A Proportionate Mortality Study of Cancer Among Kansas Farmers.**
14. **Chlorinated Dibenzo-dioxins and Dibenzo-furans in Filet of Chinook Salmon from Lake Michigan.**
15. **The Safety of Minimally Processed Refrigerated Foods.**
16. **Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk.(Iowa State University)**
17. **Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk.(Clemson University)**
18. **Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk.(Texas A&M University)**
19. **Prediction of High Risk Dietary Patterns.**
20. **Etiology and Epidemiology of Root Diseases in the Northern Rocky Mountains.**
21. **Analysis of Risk in Agricultural Decisionmaking.**
22. **Pesticide Impact Assessment Research and Data Analysis in New Mexico.**
23. **Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk.(Louisiana State University)**
24. **Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (Oklahoma State University)**
25. **Managing Multiple Chronic Health Risks From Groundwater Contamination: Theory and Application.**

26. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk.(University of Maine)
27. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk.(Pennsylvania State University)
28. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk.(Purdue University)
29. Food Safety and Animal Health.
30. The Assessment of Wellness in Women.
31. Farm Firm Decision Strategies Incorporating Risk Analysis for Cotton Producing Areas.
32. Community Risk Assessment, Technological Concerns and residential Preference.
33. Measuring, Assessing and Managing Short and Long Term Risk in Production Agriculture and Agribusiness.
34. Modeling Crop Responses and Environmental Factors Related to Shortage and Excesses of Water.
35. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (Michigan State University)
36. Scientific and Policy Basis of Risk Assessment and Risk Management.
37. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (Cornell University)
38. Risk Assessment and Texas Cattle Fever.
39. Agricultural Chemicals and Risk Assessment.
40. Epidemiology of Major Cattle, Swine, and Sheep Diseases and their Economic Consequences.
41. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (North Dakota State University)
42. Nebraska's Youth at Risk: Assessing the Problem.

43. Quantifying Long Run Agricultural Risks and Evaluating Farmer Responses to Risk. (Washington State University)
44. Comparative Quantitative Epidemiology of Tropical Plant Diseases.

**FUNDING:**

[Information being processed]

## **DEPARTMENT OF VETERAN'S AFFAIRS (DVA)**

The Department of Veterans Affairs (DVA) was established as an executive department by the Department of Veterans Affairs Act. The Department's predecessor, the Veterans Administration, had been established as an independent agency under the President by Executive Order 5398, July 1930. DVA operates programs to benefit veterans and members of their families. At the DVA, the Office of Environmental Medicine and Public Health is involved in risk assessment activities.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

1. Control of Cancer Through Familial Risk Assessment.
2. Patient's Risk Assessment for Dangerousness.
3. High Risk Assessment.
4. Pressure Sore Reduction Through Risk Assessment and Intervention.

### **FUNDING:**

[Information being processed]

2023480249

## **DEPARTMENT OF TRANSPORTATION (DOT)**

The Department of Transportation was established October 1966. Decisions made by DOT in conjunction with the appropriate State and local officials strongly affect other programs such as land planning, energy conservation, scarce resource utilization, and technological change.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

1. Risk Assessment Processes for Hazardous Materials.
2. Risk Assessment/Management Study of Rail Corridors in the City of Toronto. C 1990.

[Additional information being processed]

### **FUNDING:**

[Information being processed]

2023480250

## **CONSUMER PRODUCT SAFETY COMMISSION (CPSC)**

The Consumer Product Safety Commission (CPSC) was established by the Consumer Product Safety Commission Act, October 1972. The purpose of CPSC is to protect the public against unreasonable risks of injury from consumer products; to assist consumers to evaluate the comparative safety of consumer products; to develop uniform safety standards for consumer products and minimize conflicting state and local regulations; and to promote research and investigation into the causes and prevention of product related deaths, illnesses and injuries.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- In April 1991, the Commission proposed guidelines for cancer risk assessments and criteria for neurotoxicity and developmental and reproductive toxicity.

[Additional information being processed]

### **FUNDING:**

[Information being processed]

## **ENVIRONMENTAL PROTECTION AGENCY (EPA)**

The Environmental Protection Agency (EPA) was established pursuant to Reorganization Plan Number 3 of 1970. EPA's mission is to control and abate pollution in the areas of air, water, solid waste, pesticides, radiation, and toxic substances. EPA's mandate is to mount an integrated coordinated attack on environmental pollution in cooperation with State and local governments.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- EPA is currently in the process of revising or issuing new risk assessment guidelines for all areas of risk. EPA has published two reports arising from workshops discussing the critical issues in the revision of the risk guidelines. Among the key issues in the use of human evidence was a decision by workshop participants not to adopt a provision which would have allowed the use of human evidence to show a substance was not a human carcinogen. During 1992 it expects to issue proposed revisions to its cancer risk assessment guidelines, proposed guidelines for neurotoxicity risk assessment and general non cancer risk assessment, and final revisions to its guidelines for mutagenicity and reproductive risk assessment. EPA will also propose amendments to the developmental effects guidelines.
- EPA's Risk Assessment Council has been developing an "interim" risk characterization guidance document, which apparently would lay the foundation for the risk characterization guidance that would appear in the individual risk assessment guidelines.
- New risk assessment initiatives are being developed by the Risk Assessment Forum within the Office of Research and Development. The initiatives include agency wide guidelines for ecological risk assessments; guidelines for neurotoxins; final guidelines for reproductive effects.
- A supplemental notice to the Exposure Assessment Guidelines was published in late 1988. Because EPA's Science Advisory Board (SAB) recommended merging the supplemental notice with the 1986 Exposure Assessment Guidelines, the final amendments, which will effectively result in a revised set of exposure assessment guidelines will not appear until 1992.
- In September 1990, EPA announced that it was initiating a Relative Risk Reduction project whose goal was to develop an integrated strategy for prioritizing and addressing all environmental hazards subject to EPA jurisdiction, including high risk ecological problems, on the basis of relative risk. In introducing the program, the EPA Administrator expressed his

pleasure "that EPA's own efforts to bring more uniformity to our own risk assessments are to be reinforced by the Director of the Office of Science and Technology Policy's initiative to ensure greater coherence government wide in risk assessment." In the initial stage of the project the EPA Administrator asked each program office to select approximately 15 toxic exposures that are of greatest concern to them and targets would be set for overall reduction in those contaminants.

- EPA has also been extremely involved as a result of the 1990 Clean Air Act Amendments. Enacted in November 1990, they contain provisions for a National Academy of Science (NAS) review of EPA's risk assessment methodology for hazardous air pollutants with cancer risks or other adverse health effects "for which safe thresholds of exposure may not exist."
  - EPA, HHS and the Department of Agriculture are also working with the Executive Office of the President in developing recommendations for new food safety legislation.
1. Risk Assessment In Superfund: A Primer. First Edition, September 1990. April 1991
  2. Statistical Issues In Risk Assessment Of Reproductive Outcomes With Chemical Mixtures. 1991.
  3. Risk Assessment for Organic Micropollutants: U.S. Point of View. 1991.
  4. Risk Assessment Guidance for Superfund. Volume 1. Human Health Evaluation Manual. Supplemental Guidance: "Standard Default Exposure Factors". 25 March, 1991.
  5. Preliminary Risk Assessment for Parasites in Municipal Sewage Sludge Applied to Land. March, 1991.
  6. Quantitative Approaches to Human Risk Assessment for Noncancer Health Effects. 1990.
  7. Summary Report On Issues In Ecological Risk Assessment. February, 1991.
  8. Environmental Mutagens And Risk Assessment. 1990.
  9. Guidance For Data Useability In Risk Assessment. September 1990.
  10. Guidance For Data Useability In Risk Assessment. Interim Report. October, 1990.

11. **Seminar Publication: Risk Assessment, Management and Communication of Drinking Water Contamination. June, 1990.**
12. **Overview of Risk Assessment For Toxic and Pathogenic Agents. 1990.**
13. **Risk Assessment and Remedial Technology Effectiveness at Superfund Sites. 1990.**
14. **Ecological Risk Assessment Framework For Examining The Impacts of Oceanic Disposal. C 1990.**
15. **U-Shaped Dose Response Curves: Their Occurrence and Implications For Risk Assessment. C 1990.**
16. **Background Document to the Integrated Risk Assessment For Dioxins and Furans From Chlorine Bleaching In Pulp and Paper Mills. July 1990.**
17. **Integrated Risk Assessment For Dioxins and Furans From Chlorine Bleaching In Pulp and Paper Mills. July 1990.**
18. **Risk Assessment Guidance For Superfund. Volume 1. Human Health Evaluation Manual. Part A, April 1990.**
19. **Risk Assessment For 2378-TCDD and 2378-TCDF Contaminated Receiving Waters From U.S. Chlorine-Bleaching Pulp and Paper Mills. August 1990.**
20. **Risk Assessment, Management, Communication: A Guide To Selected Sources. Volume 3, Number 2. June 1990.**
21. **Review of Progress In The Biotechnology-Microbial Pest Control Agent Risk Assessment Program. July 1990.**
22. **Incorporating Cell Proliferation In Quantitative Cancer Risk Assessment: Approaches, Issues, and Uncertainties. February 1990.**
23. **Measurement Of Aerodynamic Size and Related Risk Assessment of Airborne Fibers. 1990.**
24. **Concepts In Ecological Risk Assessment. May 1991.**
25. **Reliability and Risk Assessment of Structures. March 1991.**
26. **In Vitro Analysis of Modulators of Intercellular Communication: Implications For Biologically Based Risk Assessment Models For Chemical Exposure.**

27. **Qualitative Risk Assessment As A Remediation Management Tool. March 1991.**
28. **Risk Assessment of New Chemical Substances. Dilution of Effluent in the Netherlands. May 1990.**
29. **Risk Assessment and Remedial Technology Effectiveness At Superfund Sites. 1990.**
30. **Exploratory Assessment of the Risk of Lung Cancer Associated With Exposure to Diesel Exhaust Based On A Study In Rats. Exploratory Diesel Risk Assessment. C 1990.**
31. **Health Risk Assessment of Pentachlorophenol (PCP) in California Drinking Water. 8 March 1990.**
32. **Overview of the Risk Assessment Study of the Dickerson Site in Montgomery County, Maryland. August 1990.**
33. **Risk Assessment Study of the Dickerson Site. Volume 3. Appendices K-N. August 1990.**
34. **Risk Assessment Study of the Dickerson Site. Volume 2. Appendices A-J. August 1990.**
35. **Risk Assessment Study of the Dickerson Site. Volume 1. Text. August 1990.**
36. **Risk Assessment Study of the Dickerson Site. August 1990.**
37. **Risk Assessment, Management, Communication: A Guide to Selected Sources. Volume 3, Number 2. June 1990.**
38. **Site Characterization and Qualitative Human Risk Assessment For The Walter Reed Army Institute Of Research Building Site, Forest Glen, Maryland. July 1990.**
39. **Uncertainty in Exposure and Health Risk Assessment: An Integrated Approach. May 1990.**
40. **Soil Climate Classification and Winter Risk Assessment for the Atlantic Region Based on Estimated Soil Temperatures. C 1990.**

41. **Environmental Risk Assessment. Foreign Trip Report, May 6, 1990-May 12, 1990. 31 May 1990.**
42. **Assessing the Geochemical Fate of Deep Well Injected Hazardous Waste.**
43. **Guidance on Remedial Actions for Superfund Sites with PCB Contamination.**
44. **Health Effects Associated with Elemental and Inorganic Phosphorous Compounds.**
45. **Development of Risk Assessment Methodology for Surface Disposal of Municipal Sludge.**
46. **Risk Assessment of Chemical Mixtures.**
47. **Development of a Qualitative Pathogen Risk Assessment Methodology for Municipal Sludge Landfilling.**
48. **Environmental Pathway Models for Estimating Population Health Effects From Disposal of High Level Radioactive Waste in Geologic Repositories.**
49. **Air Quality Criteria Document on Carbon Monoxide. 1990**
50. **Health Issue Assessment on Dimethylamine. 1990.**
51. **Risk Assessment on Electromagnetic Fields. 1990.**
52. **Health Issue Assessment on Hydrogen Cyanide. 1990.**
53. **Risk Assessment on Passive Smoking: Assessment of Lung Cancer in Adults & Respiratory Disorders in Children. 1990.**
54. **Dose Paradigms for Inhaled Vapors of Primary Carcinogens and their Impact on Risk Assessments. 1990.**
55. **Feasibility of Environmental Monitoring and Exposure Assessment for a Municipal Waste Combuster at Rutland, VT. 1991.**
56. **Histological and Histopathological Evaluation of the Testis. 1991.**
57. **Methods for Development of Inhalation Reference Concentrations. 1990.**

58. **Methodology for Assessing Health Risks Associated with Indirect Exposures to Combuster Emissions. 1990.**
59. **Presentation of Risk Assessment of Carcinogens. 1990.**
60. **Significance of DNA Damage and Repair Mechanisms in Health Risk Assessment. 1990.**

**[Additional information being processed]**

**FUNDING:**

**[Information being processed]**

**RISK ASSESSMENT  
IN THE  
PRIVATE SECTOR**

## **RISK ASSESSMENT AND MANAGEMENT COMMISSION**

The 1990 Clean Air Act Amendments established a Risk Assessment and Management Commission with a charter to review risk assessment and risk management issues relating to all federal laws and all chronic health effects. The charter goes substantially beyond the "scientific charter" of the NAS study encompassing subjects such as risk characterization, and risk management policy, as well as the "science policy" issues that are intertwined with risk assessment science.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- Under Section III of the Amendments, the Commission will be composed of ten members, three of whom will be appointed by the President, two by the Speaker of the House, one by the House Majority Leader, two by the Senate Majority Leader, one by the Senate Minority Leader and one by the President of the National Academy of Sciences. The Commission will prepare a report, after public comment, for submission to the President and the Congress, by November 15, 1994. In preparing the report, the Commission must consider the recommendations of the National Academy of Sciences study prepared under Section 301(o) of the Amendments.

### **FUNDING:**

[Information being processed]

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## **NATIONAL ACADEMY OF SCIENCES (NAS)/NATIONAL RESEARCH COUNCIL (NRC)**

The National Academy of Sciences is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Chartered by Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters.

The National Research Council was organized by the NAS in 1916 to associate the broad community of science and technology with the Academy's purposes of furthering knowledge and advising the federal government. Functioning in accordance with general policies determined by the Academy, the Council has become the principal operating agency of both the NAS and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities. The Council is administered jointly by both Academies and the Institute of Medicine.

The Institute of Medicine was established in 1970 by the NAS to secure the services of eminent members of appointed professions for the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility given to the NAS to be an adviser to the federal government, and upon its own initiative, to study problems of medical care, research, and education.

The NRC primarily provides research serving government and other organizations. As of January 1991, NRC had more than 35 major studies in progress in the overall area of environment and resources.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- More than one fourth of NAS research deals with health/environmental impacts or risk assessment, including a study evaluating both advances and opportunities in assessing the impacts of airborne pollutants. This project also outlines developments in measurements technologies, analytical and quantitative methods, biological markers, and results and on-going research with respect to specific pollutants. Another report will assess the biologic mechanisms of neurotoxicologic risk assessment, including extrapolations from one species to another.
- National Academy of Sciences Committee on Risk Assessment for Hazardous Air Pollutants (CAPRA). An amendment to Section 112 of the Clean Air Act (CAA) requires EPA to have the NAS review EPA's risk assessment methodology for hazardous air pollutants. Under Section 301 of the CAA Amendments of 1990, the report to EPA is due no later than May

15,1993. The legislation requires that the EPA Administrator (1) consider the NAS recommendations, (2) revise the existing guidelines for carcinogenic risk assessment, and (3) publish the rationale for failing to adopt any NAS recommendation for revision to EPA guidelines.

- The Board on Environmental Studies and Toxicology (BEST) of the NRC is also developing the project scope for implementing the Clean Air Act mandated study and report to EPA and Congress. The project could encompass 189 air toxics and 750 categories and subcategories of emissions sources, and since EPA must either adopt or affirmatively disavow any recommendations, the report's recommendations may be one of the most critical impacts on federal risk assessment methodologies in the 1990's.
- BEST, in consultation with the Institute of Medicine and the Commission on Physical Sciences, Mathematics, and Resources, convened a Committee on Risk Assessment Methodology (CRAM). CRAM was created as an independent body designed to help regulatory agencies develop the scientific basis, inference assumptions, regulatory applications, and research needs for applied risk assessment. CRAM, whose first meeting was held in January, 1990, gathers information primarily through a series of technical workshops.
- CRAM plans to study approximately eight topics: the use of the maximum tolerated dose; the two stage models of carcinogenesis; ecological risk assessment; physiologically-based pharmacokinetics (PB-PK) models; exposure assessment; epidemiology; developmental toxicity and issues associated with the scientific bases for risk assessment. CRAM's efforts include intensive workshops, public forums, and an annual report describing CRAM's findings. In September 1990, CRAM held a public workshop on the use of maximum tolerated dose in animal bioassays. In November 1990, it held a workshop on two stage models of carcinogenesis; and at the end of February 1991, it held a workshop on ecological risk assessment. Workshops on PB-PK modeling and exposure assessment were also undertaken in 1991. The Committee plans to complete its study on these eight topics in 1992.
- Some of the other NAS/NRC projects include: the evaluation of the exposure, health hazards, and risk assessment methods currently used by regulatory agencies in regulating exposures of infants and children to pesticide residues.
- The NAS/NRC has also explored studies of animals naturally exposed to toxic hazards as a basis for providing warning or estimating risk to human populations.

- Additionally, NAS/NRC has evaluated available methods for measuring lead exposures, with emphasis on low level detection in young children.
- The NAS/NRC issued a report designed to evaluate the scientific merit of EPA's National Human Adipose Tissue network and other efforts at systematic monitoring of human tissues. The NAS report will also recommend future monitoring efforts.
- Other new studies under consideration at NAS/NRC are on toxicity mechanisms and reactive degradation products in risk assessment and on ecological risk assessment.

**FUNDING:**

[Information being processed]

## **NATIONAL SCIENCE FOUNDATION (NSF)**

The National Science Foundation is a federal agency that provides financial and other support for research, education and related activities in science, mathematics, and engineering. NSF was created by the National Science Foundation Act of 1950 to promote awareness of science and engineering. The Foundation is independent, not part of another federal department or agency and run by a presidentially-appointed director and board. Of all the federal agencies, NSF alone has the broad mission of promoting science and engineering in general and supporting basic research across all fields and disciplines.

NSF awards grants and contracts to academic institutions, private research firms, industrial labs, and major research facilities and centers. NSF does not conduct research itself and runs no laboratories or similar facilities.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

1. Evidentiary Procedures for Carcinogenic Risk Assessment.
2. Integrated Inventory Databases for Seismic Risk Assessment.

[Additional information being processed]

### **FUNDING:**

[Information being processed]

## **RISK DIALOGUE GROUP**

The Risk Dialogue Group is an ad hoc, non chartered group of approximately 35 individuals who are knowledgeable and conversant on risk assessment, risk management and risk communications issues. The group is composed of participants from academia, federal agencies, industry, labor, research institutions, and state government. The group was formed after a risk workshop organized by the Chemical Manufacturer's Association in May 1990. Since its formation, the Dialogue Group has conducted three meetings, and will be meeting on a quarterly basis in 1992.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The Group developed a list of 10-12 possible subject areas to consider, and targeted the following four areas for further examination: improving the application of science to the risk assessment paradigm; improving exposure assessments; clarifying the appropriate uses of risk assessment; improving risk communication.
- The Group has three Risk Dialogue Group action items. These are: (1) an outline: development of a risk manager's training course; (2) a red paper on chemical risk assessment with supporting case studies; (3) a statement on improving the knowledge of risk assessment data needs and filling data gaps.

### **FUNDING:**

The Dialogue Group is funded and/or sponsored by the American Chemical Society, the American Industrial Health Council, the American Paper Institute, the Business Roundtable, the Chemical Manufacturer's Association, the Department of Defense, and the Environmental Protection Agency.

[Additional information being processed]

## **RESOURCES FOR THE FUTURE/CENTER FOR RISK MANAGEMENT**

Resources for the Future (RFF) is an independent nonprofit organization that advances research and public education in the development, conservation, and use of natural resources and in the quality of the environment. RFF was established in 1952 with the cooperation of the Ford Foundation, and is grouped into four units - the Energy and Natural Resources Division, the Quality of the Environment Division, the National Center for Food and Agricultural Policy, and the Center for Risk Management.

The Center for Risk Management was established at Resources for the Future in April 1987 with financial support from the Federal government, private foundations, and corporate sources. The Center's aim is to improve the present system by which society addresses risks to health and the environment.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The Center for Risk Management plans to concentrate on three overall goals during the next eighteen months:
  - (1) analysis of social goals, (e.g., cancer cases prevented), which guide EPA regulatory efforts compared to other public health programs such as prenatal care or smoking reduction;
  - (2) study of the difference in risk characterization between (a) the potential incidence of cancer in the population and (b) the potential risk of cancer in a single maximally exposed individual; and
  - (3) to develop and convene a conference on tradeoffs and conflicts within individual risk reduction programs.
- Center staff are also working on specific products which include, a study exploring whether society and government programs are overreacting to trivial risks and ignoring more serious ones and attempts to (1) suggest a framework for societal use of risk reduction spending and (2) determine ways for better achievement of high priority objectives.
- The Center participated in the peer review of the results of a joint EPA/Amoco project to reduce pollution risks at a 30 year old refinery.
- The Center will also be studying the possible application of benefit-cost analyses to natural resource and environmental issues, using the already established water resource methodologies as a starting point.

- Additionally, the Center is examining public attitudes toward an understanding of ecological risks, and how to employ and evaluate various methods of risk communications.

#### **FUNDING:**

RFF is currently supported by an endowment and by grants from foundations, government agencies, and corporations. Grants are accepted on the condition that RFF is solely responsible for the conduct of its research and the dissemination of its work to the public. The Center for Risk Management is broad based. The Center receives support in approximately equal parts from the federal government, private foundations, and a consortium of corporations and trade associations.

## **HARVARD SCHOOL OF PUBLIC HEALTH**

[Information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- **Harvard's Center for Risk Analysis is involved in risk analysis research, enhancing schemes for carcinogen classification, increasing use of scientific judgement in risk assessment, and improving methods for assessing maximum individual risk from exposures to toxic chemicals.**
- **Work is also continuing on the "Bright Lights" project which will study the use of numerical risk levels either codified in existing laws or proposed legislation, and evaluate the advantages and disadvantages of this legislative practice.**
- **The Center is also involved in risk conferences and workshops. They will be publishing a compendium of case studies contributed by EPA's Science Advisory Board (SAB), the Health Effects Institute, and the Chemical Industry Institute of Toxicology (CIIT) entitled, "Harnessing Science for Environmental Regulation".**
- **Every September the Center co-sponsors a three day executive course on risk analysis emphasizing key issues in cancer risk assessment, including case studies on Alar and benzene. The Center is also planning a series of symposia, including one addressing the implementation of the air toxics provisions of the Clean Air Act amendments.**

### **FUNDING:**

[Information being processed]

## **AMERICAN ASSOCIATION OF ENGINEERING SOCIETIES (AAES)**

[Information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The Risk Analysis Task Force of the AAES, an umbrella group of more than 15 engineering groups, is in the process of developing a statement on risk assessment.

[Additional information being processed]

### **FUNDING:**

[Information being processed]

## **AMERICAN CHEMICAL SOCIETY (ACS)**

The American Chemical Society (ACS) is the world's largest scientific society. Its membership of more than 140,000 chemists and chemical engineers is international. Approximately 62% of its members work in industry, but many are also in education and government. The major activity of the ACS is gathering and distributing scientific information. The ACS was founded in New York City in 1876 as a nonprofit organization. In 1937 Congress chartered the Society in the public interest. The Charter dedicates the ACS to the advancement of chemistry in all its branches, the improvement of chemists' qualifications and the promotion of scientific interests and inquiry. Congress stated that these activities would assist public welfare and education, aid the development of the country's industries and add to the comforts and happiness of the American people. ACS is governed by elected national officers, a 16 member board of directors and a nearly 500 member council.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- ACS has an ongoing public education program. The current initiative is to develop a White Paper outlining ACS' position on risk assessment issues.
- ACS is also initiating an effort to get hearings on risk assessment issues held by the Senate Environment and Public Works Committee and the House Science, Space and Technology Committee. These hearings would educate members of Congress on the issues and the basic science supporting risk assessments, as part of the ACS' ongoing education efforts dealing with risk communications.

### **FUNDING:**

[Information being processed]

2023480269

**UNIVERSITY OF MARYLAND AT BALTIMORE (UMB)**

[Information being processed]

**SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- A former EPA official is currently directing a UMB study on risk communication which analyzes the impact of the messenger on the credibility of the message. The program will attempt to determine which messengers have the greatest credibility - the media, government agencies, non profit groups, corporations. The project is expected to be completed in 1992.

[Additional information being processed]

**FUNDING:**

[Information being processed]

2023480270

## **FEDERAL FOCUS**

**Federal Focus is a non-profit Washington, D.C. Foundation formed six years ago by a former OMB official to explore and offer alternative solutions to public policy issues. [additional information being processed]**

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- **Federal Focus has spent the last two years gathering information and holding a series of seminars on risk assessment and risk management. The focal point of these efforts has been on developing a detailed draft executive order on the use and management of risk assessment by the federal government.**
- **Federal Focus recently released a report entitled, "Toward Common Measures: Recommendations for a Presidential Executive Order on Environmental Risk Assessment and Risk Management Policy".**
- **An affiliate of Federal Focus, Inc., the Institute for Regulatory Policy, is currently circulating, to interested parties, the draft Executive order on Environmental Risk Assessment and Risk Management Policy. The draft Executive order, was released in the summer of 1991.**

### **FUNDING:**

**[Information being processed]**

2023480271

## **UNIVERSITY OF ROCHESTER**

[Information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The University of Rochester is undertaking research, sponsored by the Electric Power Research Institute (EPRI), on magnetic field effects. The research is designed to determine which factors influence tumor cell growth rates in rats and in cultures of breast tumor cells. Particular investigations will focus on the mitotic activity, repair of x-ray damage, and timing of the cell cycle.

### **FUNDING:**

[Information being processed]

## **JOHNS HOPKINS SCHOOL OF HYGIENE AND PUBLIC HEALTH**

[Information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- Under a cooperative agreement between EPA and Johns Hopkins, an exposure model is being developed which can be utilized to provide an exposure profile that EPA intends to employ to develop a unit risk estimate for exposures to hexavalent chromium.
- The University has also recently begun work on a research project involving cadmium. The work is on a physiologically based toxicokinetics model for predicting cadmium kinetics in man. Although cadmium has a long biological half-life in man, existing models have not been highly successful in predicting risks from exposure.

### **FUNDING:**

[Information being processed]

## **INTERNATIONAL LIFE SCIENCES INSTITUTE (ILSI)**

A component of the International Life Sciences Institute (ILSI), the Risk Science Institute was founded in 1985 to improve the scientific basis of risk assessment.  
[Additional information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The Risk Science Institute has given a grant to Johns Hopkins University to use the same exposure data from the chromium model, to develop a sensitivity analysis based on the form and mathematical handling of the data, e.g., illustrating the difference in risk assessment number derived from data presented as either arithmetic or geometric means. This work, which is scheduled to be completed in 1992, is intended to help define more accurately what the "true" range is and what factors influence this range, in order to improve the design of future risk assessments.
- The Risk Science Institute has also given Johns Hopkins a grant to target kinetics and renal toxicity. The research would employ the data from a two year rat feeding study, based on a four dose level group and quarterly sacrifices, as the basis for developing a detailed rat model. The focus would be on the interactive effects of cadmium exposure with other metals, especially zinc and copper.
- The research will also extrapolate the results to man, using the rat model as a basis for exposure comparisons, and employing detailed epidemiological data from existing cadmium studies. The research will result in a useful predictive model for determining risk from varying levels of cadmium exposures. The University plans to complete the research in 1992.
- The Institute's current activities include a series of five regional seminars for local health professionals on the basis of risk assessment and its uses and limitations. ILSI also holds a monthly technical seminar in conjunction with the Brookings Institute and the Society for Risk Analysis.
- The Risk Science Institute has also reviewed EPA's interim guidance on dermal exposure. The Institute was responsible for assembling the reviewers and hosting a review conference. The proceedings of the latest conference focused on the relevance of animal studies in evaluating human cancer risk.

## **FUNDING:**

- **The Institute has contributed more than \$2 million for research to expand the data base used for risk assessment. The Institute has entered a cooperative agreement with the EPA to hold conferences and support risk assessment activities.[additional information being processed]**

**RISK ASSESSMENT  
IN  
INDUSTRY**

## **AMERICAN INDUSTRIAL HEALTH COUNCIL (AIHC)**

The American Industrial Health Council (AIHC) is a broad based industry association that advocates the importance of sound science in regulatory decision-making on chronic human health hazards. Founded in 1977, the avowed mission of AIHC is to ensure that state and federal regulations are based on the most credible science available and to promote the sound use of scientific principles and procedures in the assessment and regulation of risks of chronic human health effects and directly related public policy issues.

The Council's membership is a diverse coalition of companies and trade associations, including producers of consumer products, chemicals, foods and beverages, high technology, aircraft products, pharmaceuticals, petroleum products, and motor vehicles.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- Ongoing AIHC projects include a specifically targeted Science Policy Dialogue Program. Another AIHC goal is to have OSHA adopt an external Science Advisory Committee to review research and risk assessments on which OSHA regulations are based.
- AIHC supports the use of available scientific data in the risk assessment process and summarized risk assessment issues for the NAS CAPRA in a two part book.
- AIHC's more specific activities fall under two Committees
  - (1) the Scientific Committee; and
  - (2) the Science Policy Committee.
- AIHC Science Committee activities include:
  - support for a workshop on in vivo detection hosted by the Environmental Mutagen Society; completion of reports on the "Use of Human Data in Quantitative Risk Assessment of Carcinogens", and "Application of Genetic Toxicology Data in Carcinogenesis Risk Assessment"; development of a "White Paper on MTD/Dose Selection"; and
  - support of (1) the Interassociation Workshop on Mechanisms and Classification, (2) a workshop to evaluate biologic mechanisms of chemical cancer causation, (3) regulatory workshops on risk assessment for State health officials and (4) the Gordon Conference

**Workshop on in vivo Mutation Detection.**

- **The AIHC Science Policy Committee is currently involved in three initiatives: co-sponsoring a workshop on risk characterization; developing a series of risk assessment seminars for academic institutions; and preparing illustrative examples for and promoting an alternative risk assessment policy.**

**FUNDING:**

**[Information being processed]**

## **CHEMICAL MANUFACTURERS ASSOCIATION (CMA)**

[Information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- CMA has a risk communications program based on a manual it developed entitled, "Risk Communications, Risk Statistics, and Risk Comparisons". The manual is used as a basis for a two day workshop offered on an ongoing basis to teach plant managers how to approach community risk communications. The overall thrust of the program is on how to (1) develop trust and credibility within the community, (2) identify opinion leaders and appropriate forums, and (3) present the situation facing each particular facility.
- CMA is also currently engaged in a butadiene toxicology program. The project goals are to (1) develop a physiologically based pharmacokinetics model of butadiene impacts and (2) determine species based differences.
- The project will use three classes of studies to determine the dosage of BD metabolites actually delivered to target organs and will undertake to partition the metabolite coefficients (i.e., how much of the dose is delivered to the blood, liver and other organs) and determine the rate and details of metabolite processing, use results to model the amount of metabolite in each organ, particularly the liver, blood and ovaries.
- The research will focus on the delivered dose of each metabolite and then onto the target dose which actually impacts cellular DNA. The proposed structure of the research will be first on mouse studies, then on primate studies, and followed by cell level (*in vitro*) studies with human tissues, in an attempt to develop actual quantitative measurements. Once such measurements are developed, then the measurements can be used to model impacts, and develop realistic risk assessments.
- In addition, there are numerous activities specific to risk assessment that their Task Group on Risk Assessment takes part in as an active participant.

### **FUNDING:**

To date current studies and projects on butadiene have cost in excess of \$3 million. [ Additional information being processed]

## **INTERNATIONAL INSTITUTE OF SYNTHETIC RUBBER PRODUCERS (IISRP)**

[Information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The IISRP began an indepth series of animal and epidemiological studies on the possible health effects of 1,3-butadiene nearly ten years ago. IISRP is currently designing a follow-up exposure-based epidemiological study on the previous eight synthetic butadiene rubber plants, plus two additional rubber plants previously studied by the National Institute of Occupational Safety and Health (NIOSH). The study will involve 20,000 workers with a 47 year follow up period. The completion date for the study is 1994.

### **FUNDING:**

[Information being processed]

2023480280

## **AMERICAN PETROLEUM INSTITUTE (API)**

The American Petroleum Institute (API), founded in 1919, is a nonprofit corporation that represents the domestic petroleum industry. Its membership consists of a broad cross section of the petroleum and allied industries. The API's membership currently includes more than 250 domestic and foreign companies.

The objectives of the Institute are to: promote the interests of the U.S. petroleum industry; encourage the development of petroleum technology; promote environmental excellence within the industry; cooperate with government in matters of national concern; and provide information to government and to the general public on matters affecting the petroleum industry.

API activities are led by committees composed of representatives from all sectors of the industry and from companies of all sizes. Through these committees, API determines policy and positions on issues affecting the industry; plans programs and activities; deals with problems and developments of industry concern; and provides a wide range of services to member companies.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The overall basis of API efforts in the risk assessment field has generally centered on benzene, and includes both internal and joint efforts with others such as CMA and HEI. The API program has two components: (1) a longer term 3-5 year research program on benzene's toxicity mechanisms and (2) responses to EPA's assessment of benzene risk.

### **FUNDING:**

[Information being processed]

2023480281

## **FLAVOR AND EXTRACT MANUFACTURERS ASSOCIATION**

The Flavor and Extract Manufacturer's Association is comprised of approximately 11 U.S. manufacturers of flavors and extracts.

[Additional information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- As part of their position to undertake pro-active projects when it is clear a potential exposure risk occurs, the association is completing a five year project on cinnamyl anthranilate, previously used as a flavor ingredient. Earlier research had indicated this substance might create carcinogenic impacts through peroxisome proliferation. Preliminary results appear to indicate carcinogenicity, but with a limited effect unique to cinnamyl anthranilate and one other related compound. Final results are expected in 1992.

### **FUNDING:**

[Information being processed]

## **HALOGENATED SOLVENTS INDUSTRY ALLIANCE (HSIA)**

[Information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The HSIA has focused its efforts on the health impacts of chlorinated solvents and in recent years particularly upon the pharmacokinetics effects. Currently, the chemicals on which particular research is ongoing are methylene chloride, perchlorethylene, and trichloroethylene. While pharmacokinetics modeling is more accurate than the linear multistage (LMS) model in calculating risk, use of pharmacokinetics requires a far greater substance specific base.
- For these reasons HSIA is considering further research on metabolite pathways, in order to establish partition coefficients necessary for the effective use of pharmacokinetics models. After the current round of research is completed and evaluated (over the next one to two years), HSIA will determine the scope of necessary additional research.

### **FUNDING:**

[Information being processed]

2023480283

## **CHEMICAL INDUSTRY INSTITUTE OF TOXICOLOGY (CIIT)**

[Information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- CIIT has undertaken a considerable range of toxicological studies, including animal and pharmacokinetics studies. The basic goal of CIIT research is to determine the mechanisms of toxicology from a chemical-physiological basis. CIIT studies focus on individual chemicals as a means of developing more reliable biologically based models for predicting human exposure risks.
- CIIT's research program is a multi-step, chemical engineering approach which involves conducting mouse and rat studies to determine the mechanisms of biological determinants in one species, followed by studies in other species, and eventually by studies in human tissue. After the initial rodent studies, CIIT develops detailed physiologically based pharmacokinetics models for rats and mice. These models are revised and improved, based on additional species and human tissue studies, until CIIT can develop biologically based dose response models for calculating human health risk assessments.
- CIIT is currently studying 1,3-butadiene, benzene, formaldehyde, chloroform, methylene chloride, acrylonitrile, ethylene oxide and dioxin. Approximately 75% of the CIIT program is centered on chemicals that appear to pose a cancer risk. The cancer related program is divided into a four category approach based on the method of carcinogenesis (1) DNA reactive; (2) mitogenic, (3) cytotoxic, and (4) receptor mediated.
- In most cases CIIT plans a three year study life cycle, two years for the physiological studies, and an additional year to develop the risk assessment model. The studies closest to completion are those involving formaldehyde, ethylene oxide, and methylene chloride. Studies they are currently working on include 1,3-butadiene, dioxin and chloroform.

### **FUNDING:**

[Information being processed]

2023480284

## **ELECTRIC POWER RESEARCH INSTITUTE**

[Information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- In addition to the University of Rochester, EPRI is also sponsoring on going research, a mouse leukemia promotional model, at UCLA, to determine the possible promotional effects of 60-Hz fields, with or without ionizing radiation, on C57BL/6 mice. This project is apparently designed to build on an ongoing UCLA study which is exposing the same strain of mice to 60-Hz fields for 15-24 months to investigate possible leukemia effects.

### **FUNDING:**

[Information being processed]

2023480285

## **NATIONAL TOXICOLOGY PROGRAM (NTP)**

[Information being processed]

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The NTP is scheduled to begin a long term study of magnetic field effects on mice and rats in 1991.

### **FUNDING:**

[Information being processed]

2023480286

## **HEALTH EFFECTS INSTITUTE (HEI)**

The Health Effects Institute (HEI), located in Cambridge, Massachusetts, is an independent, nonprofit corporation which unites leading scientists to gather, assess, and report scientific facts to the public on complex and controversial issues of public concern. HEI was founded in 1980 to sponsor and evaluate research on the health effects of motor vehicle emissions.

A new HEI-Asbestos research group was created in 1989 to help EPA better understand the extent and significance of asbestos exposure in buildings. HEI and HEI-AR is headed by Archibald Cox, the former Watergate prosecutor and Harvard Law professor. Mr. Cox is chairman of the HEI-AR board of directors. Arthur Upton, former director of the National Cancer Institute and head of the Institute of Environmental Medicine at New York University, directs the HEI-Asbestos Research literature review.

### **SPECIFIC RISK ASSESSMENT RELATED PROJECTS AND RISK ASSESSMENTS:**

- The HEI focuses on research on health effects linked primarily to automotive emissions. Most HEI projects are generally funded for a year long effort, although follow-up studies are possible. HEI has a continuing program to determine the impacts of chronic exposure to ambient levels of ozone. The Institute is funding a study on the toxicity mechanisms of carbon monoxide. HEI is also proceeding on studies on methanol and aldehydes and it supports substance specific research and research directed at developing methodologies for improved exposure and risk assessment. Some of the HEI ongoing projects include an epidemiological planning project being done in conjunction with API, CMA, the Engine Manufacturers Association, the Motor Vehicle Manufacturer's Association, and the Gas Research Institute.
- HEI is beginning a 5 year epidemiological planning project. The project will operate through working groups on: ozone, complex mixtures, indoor air, epidemiology methods development, and electromagnetic fields (EMF). The first project is anticipated to be on ozone epidemiology. As part of an effort to improve the understanding of how to assess the toxicity of complex mixtures derived from automotive emissions, HEI will support a number of research projects in this area. The two overall goals of such research projects is to develop analytical methods to (1) separate or detect components of complex mixtures with biological impacts, and (2) determine the interactive effects of toxic components. One project, the effect of co-pollutants on the carcinogenicity of chemicals is expected this year.
- HEI will also begin a project to develop improved methodologies which can assess and quantify the risk to human health from inhalation of whole

automotive emissions and their constituents, including both in vitro and in vivo methods. Of particular interest to HEI are proposed studies that would target interactions of gases with particles in the air and the role of particles in transferring attached substances to the lung surface.

#### **FUNDING:**

HEI is beginning a 5 year epidemiological planning project with a projected budget of \$3 million, half from EPA and the other half from industry sponsors. On the HEI-AR project, a total of \$12 million has been identified through FY91. Congress provided \$2 million. [Additional information being processed]